CALIFORNIA DEPARTMENT OF PESTICIDE REGULATION PUBLIC REPORT 2007-2

Dimethenamid-P

Tracking ID Number 218783

DESCRIPTION OF ACTION

BASF Corporation submitted an application seeking California registration of Outlook Herbicide, EPA Reg. No. 7969-156, containing the new active ingredient dimethenamid-P. It is a selective pre-emergence herbicide for control of annual grasses, annual broadleaf weeds, and sedges in beets, corn, dry beans, dry bulb onions, dry bulb shallots, garlic, grain sorghum, horseradish, peanuts, perennial grasses grown for seed, potatoes, and soybeans.

The Department of Pesticide Regulation (DPR) evaluated the product label and data and found them acceptable to support conditional registration. Precautionary and first aid statements on the product labels, as well as label directions requiring personal protective equipment (PPE) and other protective measures adequately mitigate potential health risks to persons who may come in contact with the pesticide during application. DPR does not expect significant adverse environmental impacts to result from registration of Outlook Herbicide.

The U.S. Environmental Protection Agency (U.S. EPA) registered Outlook Herbicide conditionally on May 10, 1999. At that time, U.S. EPA had identified a number of labeling and data deficiencies, and required BASF Corporation to correct the deficiencies as a condition of registration. BASF Corporation complied with the conditions of registration and Outlook Herbicide was fully registered May 11, 2000.

BACKGROUND

Registrant: BASF Corporation Common name: Dimethenamid-p

Chemical name: 1(R,S)-2-chloro-N-[(1-methyl-2-methoxy)ethyl]-N-(2,4-dimethylthien-

3-yl)-acetamide

Brand name: Outlook Herbicide

Uses: For selective pre-emergence weed control of annual grasses, annual

broadleaf weeds, and sedges in a wide range of field crops

Pests controlled: Weeds such as barnyardgrass, annual bluegrass, smooth pigweed,

common purslane, and rice flatsedge

Type of registration: Conditional Registration

Outlook Herbicide is a liquid formulation containing 63.9% dimethenamid-p, which is a resolved isomer of dimethenamid. The product is a systemic chemical that inhibits root and shoot growth controlling susceptible germinating seedlings before or soon after soil emergence. Outlook

Herbicide provides the most effective weed control when applied prior to weed seedling emergence by ground or aerial equipment followed by incorporation into the soil by rainfall, sprinkler irrigation, or mechanical tillage. Because use rates of this product may vary by soil texture and organic matter, the product label recommended use rates are linked to listed soil texture groupings. Labeling prohibits application to sand-textured soil with less than 3% organic matter where depth to ground water is 30 feet or less.

SCIENTIFIC REVIEW

A. Chemistry

1. <u>Product Chemistry:</u> DPR evaluated the submitted chemistry studies for Outlook Herbicide. The results are summarized in Table I.

Table I. Physical and Chemical Properties of Outlook Herbicide				
Properties	Values			
Physical state	Liquid			
Density (20°)	1.105 grams (g)/milliliter (ml) (Bulk)			
pH (1% solution)	3.84			
Flammability	Flash Point of 154 °F (68 °C)			
Viscosity (25 °C)	25.6 cPs (25°C)			
Emission potential	19.83%			
Storage stability	Stable			
Corrosion	Non-corrosive for 2 years in HDPE and stainless			
characteristics	steel containers at 5 °C			

Submitted product chemistry data support registration of Outlook Herbicide

2. Residues in Food and Animal Feed: BASF Corporation submitted an adequate residue analytical method. The U.S. EPA established tolerances in the Code of Federal Regulations (CFR), Title 40, section 180.464 for residues of dimethenamid, 1(R,S)-2-chloro-N-[(1-methyl-2-methoxy)ethyl]-N-(2,4-dimethylthien-3-yl)-acetamide, applied as either the 90:10 or 50:50 S:R isomers, in or on the following food commodities: bean (dry, seed), beet [garden roots & tops, sugar (dried pulp, molasses, roots & tops)], field & pop corn (forage, grain, stover), sweet corn (forage, kernel plus cob with husks removed, stover), garlic, horseradish, onion dry bulb, peanut (hay, nutmeat), shallot bulb, sorghum (grain, stover, forage), soybean seed, and tuberous and corm vegetables at 0.01 ppm. When applied in accordance with the label directions, dimethenamid-p residues should not exceed the established 0.01 ppm tolerance for the listed commodities.

3. Environmental Fate: The dimethenamid-p environmental fate data included two terrestrial field dissipation studies that were conducted with Outlook Herbicide and environmental fate data for Dimethenamid-p Technical, EPA Reg. No. 7969-155. The Dimethenamid-p Technical data included studies on soil hydrolysis and aqueous soil photolysis, aerobic and anaerobic soil metabolism, anaerobic aquatic metabolism, batch equilibrium, and field dissipation. The studies were found to be satisfactory. However, when compared with the U.S. EPA and California EPA criteria for predicting the potential of a chemical to reach ground water, the submitted studies indicated that dimethenamid-p has the potential to leach, as summarized in the following table:

Table II. Comparison of U.S. EPA and DPR Ground Water Leaching Criteria with Environmental Fate Study Results for Dimethenamid-p & R,S Dimethenamid

Parameter	Potential to Leach Value (U.S. EPA)	Potential to Leach Value (California EPA)	Experimental Value	Criteria Exceeded	
Water solubility	> 30 ppm	> 3 ppm	1449 ppm	Yes	
Soil adsorption coefficient (K _d)	< 5 ml/g		1.4-3.0 ml/g	Yes	
Koc		<1,900 ml/g	105-396 ml/g	Yes	
Hydrolytic half-life	> 175 days	> 14 days	>30 days	Yes	
Aerobic soil metabolic half-life	> 21 days	> 610 days	31 days	Yes/No	
Anaerobic soil metabolic half-life	> 21 days	> 9 days	36-292 days	Yes	
Field dissipation half-life	> 21 days		6.35-17.3, 22.6. 39.5, 51.8 days (R,S- dimethenamid)	Yes	

All specific numerical values, except for aerobic soil metabolism value for California, exceed the potential leach values. The Environmental Hazards section on the product label contains extensive warnings directed at the prevention of ground water contamination. The warnings include the following: "Dimethenamid-p has properties that may result in ground water contamination. Application in areas where soils are permeable or coarse and ground water is near the surface could result in ground water contamination. Dimethenamid-p has properties that may result in surface water contamination via dissolved runoff and runoff erosion. Practices should be followed to minimize the potential for dissolved runoff and/or runoff erosion." The product label also bears specific directions for the mitigation of point source contamination, movement in runoff or through soil, and movement by water erosion of treated soil.

After an initial review of Outlook Herbicide data and labeling, including the use directions and the environmental warnings, the Environmental Monitoring Branch recommended conditional registration, pending the results of a full assessment of dimethenamid-p's potential to leach to

ground water. BASF Corporation has agreed to mitigate any potential ground water contamination hazards identified during the Environmental Monitoring Branch's assessment of dimethenamid-p.

The submitted product chemistry, residue chemistry, and environmental fate data support conditional registration of Outlook Herbicide.

B. Toxicology

BASF Corporation submitted adequate toxicology studies to conduct complete toxicological evaluations of Outlook Herbicide. DPR evaluated the submitted data to determine the potential for adverse health effects. The acute toxicity parameters for Outlook Herbicide are summarized in the following table.

Table III. Acute Toxicity of Outlook Herbicide					
Type of Study	Acute Toxicity Values	Acute Toxicity Category			
Acute oral	LD ₅₀ 429 mg/kg	II			
Acute dermal	LD ₅₀ 2000 mg/kg	III			
Acute inhalation	LC ₅₀ 2.2 mg/l	IV			
Primary eye irritation	N/A*	IV			
Primary dermal irritation	N/A	IV			
Dermal sensitization	N/A	Sensitizer			
Signal word	N/A	WARNING			
* N/A = Not applicable					

The Medical Toxicology Branch initially recommended against registration of Outlook Herbicide because the submitted data documented a dermal sensitization hazard that the product labeling did not adequately identify. In response, BASF Corporation submitted amended labeling containing an acceptable dermal sensitization statement mitigating the hazard. DPR's evaluation of the acute toxicity studies concludes that the studies are adequate to make a complete toxicological evaluation. The product label adequately identifies the potential acute toxicity hazards documented by the data reviewed. The first aid statements and PPE are adequate for the indicated acute toxicity hazards.

DPR found the submitted toxicology studies for dimethenamid-p sufficient to satisfy the data requirements of the Birth Defects Prevention Act (Food and Agricultural Code section 13121 et al.). A mutagenicity study found possible adverse effects. Possible adverse effects were also found in a rat oncogenicity study. A follow-up study was performed and the indicated effect was not observed. DPR prioritizes pesticide active ingredients for risk assessment based on of the

nature the potential adverse health effects, the number of potential adverse effects, the number of species affected, no observable effect levels (NOELs), the potential for human exposure, use patterns, and other similar factors. Based on these criteria, pesticides with the greatest potential for health problems are placed in high priority, with other chemicals being in moderate or low priority. At this time, DPR gives dimethenamid-p a moderate priority for risk assessment. The purpose of the risk assessment would be to appraise the potential for dimethenamid-p to cause adverse health effects in humans if exposed to the pesticide through legal use. A summary of Toxicology Data with additional dimethenamid-p toxicity information is available on the DPR public website at: http://www.cdpr.ca.gov/docs/toxsums/pdfs/5919.pdf.

C. Health & Safety

DPR's evaluation of the medical management information on the Outlook Herbicide label and the acute toxicity study results indicate that the product label bears all of the required statements and warnings regarding safety to handlers and other persons who may be exposed to the pesticide. The product label bears an adequate First Aid statement. In addition, the product label requires applicators and other handlers to wear long sleeved shirt and long pants, chemical resistant gloves, shoes plus socks, and protective eyewear. The instructions for applicators and handlers direct them to discard clothing and other absorbent materials that have been drenched or heavily contaminated with product concentrate, and to not re-use them. In addition, the instruction is given to wash PPE separately from other laundry. Mixers and loaders for aerial applications must use a closed system that meets the requirements listed in the Worker Protection Standard (WPS) for Agricultural Pesticides (40 CFR 170.240 (d)(4) for dermal protection, and must wear personal protective equipment required in the PPE section of the labeling for applicators and other handlers. They must wear protective eyewear if the system operates under pressure, and must either use a closed system that also meets the requirements in the WPS for inhalation protection or wear a NIOSH approved dust-mist respirator with a TC-84 cartridge.

D. Fish & Wildlife

The registrant submitted fish and wildlife toxicity studies, including studies on bobwhite quail, mallard ducks, bluegill sunfish, rainbow trout, *Daphnia magna*, sheepshead minnow, mysid shrimp, and oysters. The submitted data are adequate to characterize the toxicity to wildlife and aquatic animals from an environmental exposure. Table IV summarizes the results of these studies (see page 6).

The data indicate that dimethenamid-p is relatively non-toxic to birds, slightly toxic to bluegill sunfish, sheepshead minnow, and *Dapnia magna*, and moderately toxic to rainbow trout, oysters, and mysid shrimp. To mitigate the hazards to aquatic organisms the Outlook Herbicide label contains the Environmental Hazards warning, "Do not apply directly to water, areas where surface water is present, or inter-tidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwater or rinsate."

Test Animal	Type of Study	Acute Toxicity Value**	Relative Toxicity
Bobwhite quail	Single acute oral dose	>1068 mg/kg (LD ₅₀)	Relatively non-toxic
Mallard duck	Feeding study (5 day)	>5620 ppm (LC ₅₀)	Relatively non-toxic
Bobwhite quail	Feeding study (5 day)	>5620 ppm (LC ₅₀)	Relatively non-toxic
Bobwhite quail	Reproduct study (20 wk)	900 ppm NOEC	
Mallard duck	Reproduct study (20 wk)	1,800 ppm NOEC	Relatively non-toxic
Bluegill sunfish	Water exposure (96 hrs)	10 mg a.i./l (LC ₅₀)	Slightly-toxic
Rainbow trout	Water exposure (96 hrs)	6.3 mg a.i./l (LC ₅₀)	Moderately-toxic
Rainbow trout	Water exposure (21 dys)	3.22 mg a.i./l (LC ₅₀)	Moderately-toxic
Rainbow trout	Water exposure (90 dys) early life stage	0.12 mg a.i./l NOEC	
Dapnia magna	Water exposure (48 hrs)	12.0 mg a.i./l (LC ₅₀)	Slightly-toxic
Dapnia magna	Water exposure (21 dys)	1.36 mg a.i/l NOEC	
Sheepshead minnow	Water exposure (96 hrs)	12 mg a.i./l (LC ₅₀)	Slightly-toxic
Mysid shrimp	Water exposure (96 hrs) flow-through	3.2 mg a.i./l (LC ₅₀)	Moderately-toxic
Mysid shrimp	Water exposure (96 hrs) static conditions	4.8 mg a.i./l (LC ₅₀)	Moderately-toxic
Eastern oyster	Water exposure (96 hrs)	5.0 mg a.i./l (EC ₅₀)	Moderately-toxic

^{*} The test substance used for the studies was the technical active ingredient.

E. Efficacy & Phytotoxicity

Dimethenamid is in the group of acetamide pre-emergence herbicides that are used to control annual grasses, sedges, and broadleaf weeds in a variety of crops. The primary site of absorption and action on broadleaf species are the roots. The primary site of absorption and action on grass species is the emerging shoot. The acetamides are not readily translocated in plants, so herbicide placement and availability is important. The mechanism of action of this group of herbicides has not been well defined, but they appear to interfere with normal cell development.

Submitted efficacy and phytotoxicity studies indicate that Outlook Herbicide provides effective pre-emergence control of many problem weeds in a number of crops including sugar beets, corn,

^{**} Acute Toxicity Values expressed as:

 LD_{50} = Lethal dose that kills 50% of the test population

 LC_{50} = Lethal environmental concentration that kills 50% of the test population

 EC_{50} = Concentration of a toxicant causing a defined non-lethal effect in 50% of the test population

dry beans, onions, shallots, garlic, grain sorghum, peanuts, and potatoes. Product labeling allows air and ground equipment application at a maximum of 21 fluid ounces (1 lb. a.i.) per acre per season. The product label contains a table of application rates recommended for different soil texture and organic matter content. Efficacy of Outlook is not improved by use of spray adjuvants. However, Outlook may be tank mixed with one or more pesticides, and a tank mix with a post-emergence herbicide must be used if weed growth is present at the time of application. The Outlook label contains directions for jar testing to determine compatibility of Outlook with other pesticides (fungicides, herbicides, insecticides, or miticide). Submitted product efficacy and phytotoxicity data are adequate to support registration of Outlook Herbicide.

ALTERNATIVES

Outlook Herbicide is a liquid herbicide providing pre-emergence control of a broad range of weedy annual grasses, sedges, and annual broadleaves found in beets, corn, dry bean, dry bulb onions, dry bulb shallots, garlic, grain sorghum, horseradish, peanuts, perennial grasses grown for seed, potatoes, and soybeans. It is effective as a tank mix with a wide variety of approved pesticides. Key advantages of Outlook Herbicide are that a large number of crops show good tolerance, it is effective against a broad range of weeds, and it is compatible as a tank mix with many other pesticides (fungicides, herbicides, insecticides, or miticide). Outlook Herbicide is especially useful for control of yellow nutsedge in dry bulb onions. Yellow nutsedge is a difficult weed to control, and because onions have a good tolerance to dimethenamid-p, Outlook Herbicide can be used at the higher rates that are necessary to control yellow nutsedge. A number of other active ingredients are registered as pre-emergence herbicides. However, an effective integrated pest management strategy requires the flexibility of a large number of comparable, but not exactly equivalent, pesticides in order to reduce the development of resistance.

CONCLUSION

DPR evaluated the product label and scientific data submitted to support the registration of Outlook Herbicide. The label and data were found acceptable to support conditional registration. The acute health risks to human from exposure to dimethenamid-p are minimal due to its low mammalian toxicity. The precautionary and first aid statements on the product label and the recommended protective measures mitigate potential health risks to persons who may be exposed to these pesticides. If a risk assessment conducted by DPR determines that exposure to dimethenamid-p may result in unacceptable margins of exposure, DPR will place further restrictions on the use of dimethenamid-p at that time. Submitted data indicate that dimethenamid-p may have the potential to leach to ground water. However, no significant adverse environmental impacts are expected to occur from the use of Outlook Herbicide, and when used in accordance with label directions, it will be effective for the intended use.

After an initial review of Outlook Herbicide data and labeling, including the use directions and the environmental warnings, the Environmental Monitoring Branch recommended conditional

registration for Outlook Herbicide, pending the results of a full assessment of dimethenamid-p's potential to leaching to ground water. In accordance with the conditions of registration, BASF Corporation has agreed to mitigate any potential ground water contamination hazards that DPR identifies.